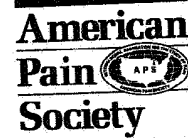


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Exhibit 78



The Use of Opioids for the Treatment of Chronic Pain



A consensus statement from the American Academy of Pain Medicine and the American Pain Society

I. The management of pain is becoming a higher priority in the United States.

In the last several years, health-policymakers, health professionals, regulators, and the public have become increasingly interested in the provision of better pain therapies. This is evidenced, in part, by the U.S. Department of Health and Human Services' dissemination of Clinical Practice Guidelines for the management of acute pain and cancer pain. These publications, which have been endorsed by AAPM and APS, state that opioids, sometimes called "narcotic analgesics," are an essential part of a pain management plan. There is currently no nationally accepted consensus for the treatment of chronic pain not due to cancer, yet the economic and social costs of chronic pain are substantial, with estimates ranging in the tens of billions of dollars annually.

II. Current conditions dictate the need for a joint consensus statement of two major national pain organizations.

AAPM and APS believe that the United States is in a critical phase of state-level policy development with respect to the use of opioids in pain treatment. In this regard, there has been recent activity in state legislatures (i.e., intractable pain treatment acts and the establishment of pain commissions) and at the regulatory level (statements of policy from state boards of medical examiners). In response to inquiries from concerned boards, AAPM and APS wish to encourage a dialogue with regulators about the appropriate relation between law and the practice of pain medicine. The purpose of laws that govern controlled substances and professional conduct is to protect the public. Our objective is for state policies to recognize but not interfere with the medical use of opioids for pain relief, while continuing to address the issue of prescribing that may contribute to drug abuse and diversion.

It is imperative that this statement not be misconstrued as advocating the imprudent use of opioids. Rather, if a practitioner decides to treat chronic pain with opioids, this document should serve as a guide for both the practitioner and regulators with regard to the judicious use of these drugs in the course of medical practice.

III. Pain is often managed inadequately, despite the ready availability of safe and effective treatments.

Many strategies and options exist to treat chronic noncancer pain. Since chronic pain is not a single entity but may have myriad causes and perpetuating factors, these strategies and options vary from behavioral methods and rehabilitation approaches to the use of a number of different medications, including opioids.

Pain is one of the most common reasons people consult a physician, yet it frequently is inadequately treated, leading to enormous social cost in the form of lost productivity, needless suffering, and excessive healthcare expenditures.

Impediments to the use of opioids include concerns about addiction, respiratory depression and other side effects, tolerance, diversion, and fear of regulatory action.

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IV. Current information and experience suggest that many commonly held assumptions need modification.

Addiction: Misunderstanding of addiction and mislabeling of patients as addicts result in unnecessary withholding of opioid medications. Addiction is a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, the continued use of which results in a decreased quality of life. Studies indicate that the de novo development of addiction when opioids are used for the relief of pain is low. Furthermore, experience has shown that known addicts can benefit from the carefully supervised, judicious use of opioids for the treatment of pain due to cancer, surgery, or recurrent painful illnesses such as sickle cell disease.

Respiratory depression and other side effects: Fear of inducing respiratory depression is often cited as a factor that limits the use of opioids in pain management. It is now accepted by practitioners of the specialty of pain medicine that respiratory depression induced by opioids tends to be a short-lived phenomenon, generally occurs only in the opioid-naïve patient, and is antagonized by pain. Therefore, withholding the appropriate use of opioids from a patient who is experiencing pain on the basis of respiratory concerns is unwarranted. Other side effects, such as constipation, can usually be managed by attention to diet, along with the regular use of stool softeners and laxatives. Sedation and nausea, possible early side effects, usually dissipate with continued use.

Tolerance: It was previously thought that the development of analgesic tolerance limited the ability to use opioids efficaciously on a long-term basis for pain management. Tolerance, or decreasing pain relief with the same dosage over time, has not proven to be a prevalent limitation to long-term opioid use. Experience with treating cancer pain has shown that what initially appears to be tolerance is usually progression of the disease. Furthermore, for most opioids, there does not appear to be an arbitrary upper dosage limit, as was previously thought.

Diversion: Diversion of controlled substances should be a concern of every health professional, but efforts to stop diversion should not interfere with prescribing opioids for pain management. Attention to patterns of prescription requests and the prescribing of opioids as part of an ongoing relationship between a patient and a healthcare provider can decrease the risk of diversion.

V. Policy is evolving.

State law and policy about opioid use are currently undergoing revision. The trend is to adopt laws or guidelines that specifically recognize the use of opioids to treat intractable pain. These statements serve as indicators of increased public awareness of the sequelae of undertreated pain and help clarify that the use of opioids for the relief of chronic pain is a legitimate medical practice.

VI. Accepted principles of practice for the use of opioids should be promulgated.

Due to concerns about regulatory scrutiny, physicians need guidance as to what principles should generally be followed when prescribing opioids for chronic or recurrent pain states. Regulators have also expressed a need for guidelines to help them to distinguish legitimate medical practice from questionable practice and to allow them to appropriately concentrate investigative, educational, and disciplinary efforts, while not interfering with legitimate medical care.

VII. Principles of good medical practice should guide the prescribing of opioids.

AAPM and APS believe that guidelines for prescribing opioids should be an extension of the basic principles of good professional practice.

Evaluation of the patient: Evaluation should initially include a pain history and assessment of the impact of pain on the patient, a directed physical examination, a review of previous diagnostic studies, a review of previous interventions, a drug history, and an assessment of coexisting diseases or conditions.

Treatment plan: Treatment planning should be tailored to both the individual and the presenting problem. Consideration should be given to different treatment modalities, such as a formal pain rehabilitation program, the use of behavioral strategies, the use of noninvasive techniques, or the use of medications, depending upon the physical and psychosocial impairment related to the pain. If a trial of opioids is selected, the physician should ensure that the patient or the patient's guardian is informed of the risks and benefits of opioid use and the conditions under which opioids will be prescribed. Some practitioners find a written agreement specifying these conditions to be useful.

An opioid trial should not be done in the absence of a complete assessment of the pain complaint.

Consultation as needed: Consultation with a specialist in pain medicine or with a psychologist may be warranted, depending on the expertise of the practitioner and the complexity of the presenting problem. The management of pain in patients with a history of addiction or a comorbid psychiatric disorder requires special consideration, but does not necessarily contraindicate the use of opioids.

Periodic review of treatment efficacy: Review of treatment efficacy should occur periodically to assess the functional status of the patient, continued analgesia, opioid side effects, quality of life, and indications of medication misuse. Periodic reexamination is warranted to assess the nature of the pain complaint and to ensure that opioid therapy is still indicated. Attention should be given to the possibility of a decrease in global function or quality of life as a result of opioid use.

Documentation: Documentation is essential for supporting the evaluation, the reason for opioid prescribing, the overall pain management treatment plan, any consultations received, and periodic review of the status of the patient.

VIII. The Mission Statements of AAPM and APS are consistent with this collaborative effort.

The American Academy of Pain Medicine is the AMA-recognized specialty society of physicians who practice pain medicine. The American Pain Society is the national chapter of the International Association for the Study of Pain and is composed of physicians, nurses, psychologists, scientists, and members of other disciplines who have an interest in the study and treatment of pain.

The mission of the American Academy of Pain Medicine is to enhance pain medicine practice in this country by promoting a socioeconomic and political climate conducive to the effective and efficient practice of pain medicine and by ensuring quality medical care by physicians specializing in pain medicine, for patients in need of such services.

The mission of the American Pain Society is to serve people in pain by advancing research, education, treatment, and professional practice.

The undertreatment of pain in today's society is not justified. This joint consensus statement has been produced pursuant to the missions of both organizations, to help foster a practice environment in which opioids may be used appropriately to reduce needless suffering from pain.

The statement was prepared by the following committee members: J. David Haddox, DDS MD (Chair); David Joranson, MSSW (Vice Chairman); Robert T. Angarola, Esq.; Albert Brady, MD; Daniel B. Carr, MD; E. Richard Blonsky, MD; Kim Burchiel, MD; Melvin Gitlin, MD; Matthew Midcap, MD; Richard Payne, MD; Dana Simon, MD; Sridhar Vasudevan, MD; Peter Wilson, MBBS, PhD.

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Approved by the AAPM Board of Directors on June 29, 1996

Approved by the APS Executive Committee on August 20, 1996

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